

EDITORIAL

Informed consent in Leprosy Studies

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*‘Being human means being conscious and being responsible’*¹

Quoted in ‘To Heal a Fractured World: the ethics of responsibility’ by Jonathan Sacks.²

LEPROSY CONTROL AND POLICY

The control of leprosy continues to be an international health problem with a need to study and conduct research in many areas of leprosy control from treatment, to prevention of disabilities, to the social determinants of the disease. The ‘Enhanced Global Strategy for 2011 – 2015’ to further reduce the leprosy disease burden has been adopted and is being implemented by national leprosy programmes in countries where the disease is endemic. The strategy aims to reduce the rate of new cases with Grade-2 disabilities (visible disabilities) worldwide by $\geq 35\%$ by the end of 2015. The WHO document indicates that the target is expected to help national programmes sustain their leprosy control activities and to monitor progress towards further reducing the disease burden.³ Within this strategy there are many research questions.

Leprosy research requires different disciplines perspective and tools, from immunology, with a focus on cells, to anthropology with a focus on individuals, to epidemiology with a focus on populations and finally to policy with its focus on power and process. The common factor in all these disciplines is that they need people with leprosy, their families, their communities and the health care workers in the health systems, to agree to be involved in the research. If a person is to be involved in a research study, then their consent needs to be sought and acquired. A focus on the individual is essential and that is why the focus for the ethics of research is on protecting the rights of the individual study subject.⁴

BEGINNING THE RESEARCH PROCESS

At the start of the research process each researcher needs to think about and reflect on the broad context in which his/her study has been created and in how the study may affect individuals and communities.⁵ For example, crossing social and cultural boundaries is a challenge for all researchers whether we are conducting research in a different part of our own country or

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another country. Ethics, the rights and wrongs of how we do things,⁶ tends to highlight our differences and perspectives and, in doing so, challenges the way we see things. For example, when working between countries it is important to realize that health priorities may be different, and ways of perceiving and seeing diseases like leprosy, may also differ. In addition, each country will have different processes, priorities and methods for conducting research and for ways to obtain 'informed consent.'^{5,7}

Further reflection on the research process can continue with self-reflective questions like: 'Who am I in this research study?' 'Who am I with?' And 'what is my place?'⁸ 'Who am I?', for example, may relate to where you are from and the particular perspectives that you bring to the research. For example, you may be an immunologist with a focus on vaccine development, or an epidemiologist studying the incidence of leprosy in a community. 'Who am I with?' might relate to your research team, but it could also be about the community that you are working with in the research study. 'What is my place?' might be about your role as a leader of your research team or your responsibility for maintaining the credibility of your organisation and ensuring that appropriate governance procedures are followed in the research.

The ethics of research within an academic or other research organisation comes under the governance framework for that organisation. Governance is associated with rules and collective action. These rules may be formal or informal and provide incentives and constraints to certain types of behaviour.⁹ So governance is a process; 'the process by which organisations, corporations, societies and other actors guide themselves. It is about how these bodies interact with each other and with their stakeholders.'¹⁰ Informed consent is a part of these governance processes.

WHAT IS 'INFORMED CONSENT'?

According to the Oxford English Dictionary, to be 'informed' means 'having good or sufficient knowledge of something' and consent means 'to say that one is willing to do or allow what someone wishes.' Bringing the two words together provides a framework for action and points towards a process which results in an agreement.

RELATIONSHIP AND INFORMED CONSENT

So, consent is about the creation of a relationship in which the discussion is about one person doing something for another. Charles Fried has identified the four fundamental characteristics of an authentically human relationship as: humanity, autonomy, lucidity and fidelity.^{11,12} These characteristics are essential qualifications of how clinical investigators, physicians, patients and subjects should try to behave towards each other. In a human relationship, a person is not treated simply as one of a group but as a unique individual. 'The characteristic, *humanity*, stresses that each person is unique with a corresponding unique biology, needs, weaknesses, strengths, and life plans.' *Autonomy* is about self-determination and the need and capacity to deliberate about personal goals. Consent is about an agreement between two individuals who are free to act as they believe appropriate. *Lucidity*, 'shining a light' on something, ensures that communication is honest, frank and open to imparting all know information that is necessary to another's self-determination and choices and *fidelity* means faithfulness in responding to certain expectations that are an essential and integral part of a relationship.¹²

Consent is also about *the process* of a relationship and how it develops and the process feeds back onto the person who is acquiring consent and reflects back on their own

internalised ethical processes.¹³ Both the researcher and the potential study subject come from families, communities, work institutions and from countries with particular cultural characteristics. Through the process and discussion around 'informed consent' these different perspectives and paradigms have an opportunity to speak and to be heard. They help to ensure that the link between research and study subject continues throughout the study until it has been completed with the feedback of results to individuals and their communities.

INFORMED CONSENT: DECLARATIONS, CODES AND REGULATION

Respect for human beings and the protection of their dignity, autonomy, rights, needs and interests are at the core of many of the codes and guidelines governing the ethics of research since World War II. The Nuremberg Code for example records the essential characteristics of consent required to protect the autonomy of each human being involved in medical research: 'Their consent has to be competent, voluntary, informed and comprehending.'¹⁴

An essential document to read on informed consent is the Helsinki Declaration which highlights the important ethical challenges within research and the ways to ensure that the research process is appropriate.⁴ Although the Declaration is addressed primarily to physicians, the World Medical Association (WMA) encourages other participants in medical research involving human subjects to adopt these principles. There are 35 statements within the Declaration; point 6 states 'In medical research involving human subjects, the well being of the *individual research subject* must take precedence over all other interests.' Ensuring the safety of the research participants is at the core of the Declaration and points 22-29 all relate to informed consent. Point 22 states 'Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.' The focus is therefore on the autonomy of the individual. Point 23 addresses confidentiality and minimising physical, mental and social integrity and points 24 and 25 state that each subject must be adequately informed of the aims, methods, funding, conflicts of interest, institutional affiliation, risk and benefits of the study as well as provided with information on the collection, analysis and storage of information. Finally, points 26 – 29 indicate the approach to be taken with physician dependent relationships and in those people who are mentally incapable of giving consent.⁴

INFORMATION REQUIRED FOR CONSENT TO BE 'INFORMED'

Other International Organisations like the Council for International Organisations of Medical Sciences,¹⁵ the Council of Europe,¹⁶ and the Nuffield Council on Bioethics,¹⁷ have all published guidelines on international research and all address the issue of consent. The areas they cover include: who should give consent, how it should be recorded, provision of information, inducements, and concepts of 'genuine consent.' The degree of detail of information required, however, varies between the guidelines, and indicates the increasing bureaucracy around international trials. As consent becomes an increasingly bureaucratic process, there is a potential to completely miss the point of consent, namely the creation of relationship.

Overall, the guidelines agree that a prospective participant in research must be provided with information about the proposed research before any consent to participate can be considered valid. According to the Nuffield Council on Bioethics, the ethically significant

requirement is that consent to research be genuine' (page 71). They point out that 'the apparent genuineness of consent can be defeated by a number of circumstances, including coercion, deception, manipulation, deliberate mis-description of what is proposed, lack of disclosure of material facts or conflicts of interest' and the guidelines describe what to do in these particular situations (page 72). For example, there needs to be clarity/lucidity about 'inducements' in order to ensure that individuals know and feel that the process is voluntary and that they are not being coerced into doing something that they would prefer not to do.

RECORDING CONSENT

The Nuffield Council makes it clear that it is the *process* for obtaining informed consent that is important, rather than the procedure used to record or document the process' (page 80). 'The purpose of a consent form is to record what has been agreed between the researcher and the participant' (page 81). If it is inappropriate for a person to sign a form, then other means of recording would be appropriate. For example, taping a response, or witnessing a response (page 82 and 83).

Some guidelines stress the importance of respecting cultural beliefs and norms, which means that in certain situations community consent, rather than individual consent, is also possible and appropriate. Again, finding an appropriate way of recording the process of community consent is important.

CONCLUSION

As researchers into the disease of leprosy, each of us is *responsible* for the process of our research. We have a duty to ourselves, our participants and our institutions to ensure that the work we do, the relationships that we develop and the outcomes that are achieved ensure the rights and dignity of each individual study subject. The ethical framework used by the Nuffield Council in their report in 2002 (page 50) emphasises the duties of research: the duty to alleviate suffering; the duty to show respect for persons; the duty to be sensitive to cultural differences; and the duty not to exploit the vulnerable. The process of acquiring informed consent lies at the heart of these duties.¹⁷

Sometimes researchers seem to see 'obtaining informed consent' as some kind of legally imposed ritual as though consent is something *they* need for *their* research. 'They fail to grasp the reality that adequate information is primarily a need of the patient (or study subject) and a moral requirement of integrity in a human relationship.'¹² To respect another human being requires each of us to balance our relationship, to be aware of the biased perspectives we can bring to the relationship and not to judge this other person.

As individual researchers and as leaders of teams of researchers we need to be conscious and responsible for our actions and those of our teams and we need to create positive intentions around the ethics of our work. How 'informed consent' is obtained will reflect on the values of the research team and its ability to conduct research that respects the dignity and difference of each individual within a research study.

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